

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA,)	
)	
)	
Plaintiff,)	Civil Action No. 02-CV-9236
v.)	Civil Action No. 03-CV-5425
)	
ADVANCEPCS, a Delaware Corporation,)	
)	
)	
Defendant.)	
_____)	

CONSENT ORDER OF COURT FOR INJUNCTION AND SETTLEMENT

Plaintiff United States of America, acting through the United States Department of Justice and the United States Attorney's Office for the Eastern District of Pennsylvania, asserts a claim for injunctive relief under the Federal Injunctive Statute, 18 U.S.C. § 1345, against AdvancePCS, a wholly owned subsidiary of Caremark Rx, Inc., and having consented to the entry of the instant Consent Order of Court for Injunction and Settlement ("Consent Order" or "Order") for the purposes of settlement of the United States' claim for injunctive relief, without this Order constituting evidence against or any admission by any party, and without trial of any issues of law or fact, with respect to covered conduct as identified herein, NOW THEREFORE, upon the consent of the parties hereto, IT IS HEREBY ORDERED, ADJUDGED AND DECREED AS FOLLOWS:

I. PARTIES

- A.** The United States is the plaintiff in this case.
- B.** AdvancePCS is the defendant in this case. AdvancePCS is a pharmaceutical services company that administers pharmacy benefit management services for health plans and

employers, including governmental employers, aimed at reducing the costs and improving the safety and effectiveness of prescription drug use.

II. JURISDICTION & VENUE

A. This Court has jurisdiction over the subject matter of this case and of the parties consenting hereto for the purposes of entering into and enforcing this Order pursuant to 18 U.S.C. § 1345. The Court may grant declaratory and other relief necessary to enforce this Order pursuant to 18 U.S.C. § 1345.

B. Venue is proper as to all parties in the United States District Court for the Eastern District of Pennsylvania.

C. AdvancePCS has conducted business in the Eastern District of Pennsylvania by providing pharmacy benefit management services to clients within the district.

III. PREAMBLE

A. The instant Consent Order addresses the United States' civil claim for injunctive relief under 18 U.S.C. § 1345.

B. The United States has investigated certain business practices of AdvancePCS in place from 1996 until January 27, 2004, including its solicitation and receipt of rebates and other amounts from drug manufacturers, its negotiation of contracts with client health plans, its placement of drugs on its national formulary and preferred drug list, its use of brokers and consultants, its relationship with retail networks, and its drug interchange practices.

C. The United States may obtain injunctive relief under 18 U.S.C. § 1345 with respect to AdvancePCS' business practices.

D. AdvancePCS has, by signature of its counsel hereto, waived any right to appeal, petition for certiorari, or move to reargue or rehear this judgment and order. Entry of this Order is in the public interest.

E. Entry of this Order does not constitute a finding of liability against AdvancePCS and AdvancePCS denies any and all allegations. Rather, to avoid the delay, expense, inconvenience, and uncertainty of protracted litigation of the United States' claim for injunctive relief, the United States and AdvancePCS have consented to the entry of the instant Consent Order for the purposes of this settlement only, without this Order constituting evidence against or any admission by any party, and without trial of any issue of fact or law on the issues specifically addressed and released herein.

IV. DEFINITIONS

Defined Terms include:

“AdvancePCS” shall mean PCS Health Systems, Inc., Advance Paradigm, Inc., and AdvancePCS, and its subsidiaries, including all state licensed pharmacy subsidiaries, and its corporate predecessors.

“AdvancePCS Total Product Revenue” shall mean AdvancePCS and its corporate affiliates' net revenue which consists principally of sales of prescription drugs to clients, either through network of contractually affiliated retail pharmacies or through mail order pharmacies, including any specialty pharmacies. Where AdvancePCS or its corporate affiliates act as a principal in accordance with generally accepted accounting principles, which is the case in the majority of AdvancePCS and its corporate affiliates' client contracts, revenues are recognized at the prescription price negotiated with clients, as well as the associated administrative fees.

“Client Plan” shall mean any governmental entity, employer, insurer, union or other entity that contracts with AdvancePCS to provide or administer a pharmacy benefit for such client plan and its Plan Participants.

“Confidential Information” shall mean the confidential and proprietary information of AdvancePCS, including, but not limited to, costs and pricing, rebate agreements, financial and technical information, ideas, designs, specifications, techniques, models, data, programs, documentation, processes, know-how, customer lists, marketing plans; information regarding contracts, audit results, SAS70 reports, pricing, finances, discounts or rebates; manuals; computer programs, systems and capabilities; databases, innovations and copyrighted materials; trade secrets; the value of which might be lost if the proprietary nature or confidentiality of such Confidential Information is not maintained.

“Drug Interchange” shall mean any change from one prescription drug to another, requested by or on behalf of AdvancePCS. “Drug Interchange,” however, shall not include those Drug Interchanges:

- i) initiated pursuant to a drug utilization review;
- ii) initiated for Plan Participant safety reasons;
- iii) required due to market unavailability of the Originally Prescribed Drug;
- iv) from a brand drug to its Generic Equivalent; or
- v) required for coverage reasons, that is, where the Originally Prescribed

Drug is not covered by the Client Plan.

“Drug Interchange-Related Health Care Costs” shall mean a Plan Participant’s co-pay incurred for tests, doctor visits, and other health care services that are performed in accordance with a treating physician’s instructions, and are incurred as a direct result of a Drug

Interchange, for the purpose of assessing the continuum of the previous therapy, for up to 30 days following a Drug Interchange. If, following a Drug Interchange solicitation, a Prescriber or Plan Participant indicates that a proposed Drug Interchange will result in such costs being incurred, AdvancePCS in its discretion may cease to seek the proposed Drug Interchange. If a Plan Participant, because of a deductible or cap requirement, pays actual costs of tests instead of co-pays, then that Plan Participant's Drug Interchange-Related Health Care Costs shall be based on the co-pay (if any) that would apply upon satisfaction of the deductible or the co-pay applicable prior to the cap being met.

"Generic Equivalent" shall mean a medication deemed chemically equivalent to a branded drug, signified by an A rating by the Food and Drug Administration, approval for substitution on an applicable formulary, or approval for substitution by the P&T Committee.

"Manufacturer Payments" shall mean any compensation or remuneration AdvancePCS and its corporate affiliates receive from or on behalf of a pharmaceutical manufacturer, including but not limited to, rebates, regardless of how categorized, market share incentive, commissions, fees under products and services agreements, any fees received for sales of utilization data to a pharmaceutical manufacturer, and administrative or management fees. It does not include purchase discounts based upon invoiced purchase terms. For purposes of AdvancePCS' "Manufacturer Payment Reports" provided to Clients Plans hereunder, all "Manufacturer Payments" received by AdvancePCS and its affiliates fit into one of two categories defined herein, namely, "Manufacturer Formulary Payments" or "Manufacturer Additional Payments."

“Manufacturer Formulary Payments” shall mean Payments that AdvancePCS and its affiliates receive from a manufacturer in return for formulary placement and drug utilization pursuant to AdvancePCS and its affiliates’ agreements with pharmaceutical manufacturers.

“Manufacturer Additional Payments” shall mean all Manufacturer Payments other than Manufacturer Formulary Payments.

“NTI” or “NTR” shall mean Narrow Therapeutic Index (“NTI”) or Narrow Therapeutic Range (“NTR”) drug, defined by the Food & Drug Administration as a drug for which there is less than a 2-fold difference in median lethal dose (LD50) and median effective dose (ED 50) values or, there is less than a 2-fold difference in the minimum toxic concentrations and minimum effective concentrations in the blood, and safe and effective use of the drug product requires careful titration and patient monitoring.

“Originally Prescribed Drug” shall mean a drug prescribed for a Plan Participant that is the subject of a AdvancePCS Drug Interchange solicitation.

“Plan Participant” shall mean a natural person whose prescription drug benefit is administered by AdvancePCS.

“Prescriber” means a physician, dentist, physician’s assistant, optometrist or other health care professional authorized by law to write prescriptions for prescription drugs.

“Usual and Customary” or “U&C” shall mean usual and customary retail cash charges.

V. GENERAL TERMS AND PROVISIONS

A. AdvancePCS will not advise or counsel Client Plans to develop, design or implement a plan design for prescription drug benefits for its Plan Participants that is inconsistent with the terms of this Consent Order. This Consent Order shall not operate or be

construed, however, to limit the ability of a Client Plan to develop, design, or implement a plan design for prescription drug benefits for its Plan Participants, subject to its duty to comply with applicable laws and regulations.

B. No disclosure of Confidential Information shall be required pursuant to this document in the absence of a contract that is signed and executed by each party with the authority to bind the respective party to the terms of the contract. Prior to any disclosure of Confidential Information required pursuant to this document a confidentiality agreement must be signed by client/payers, employees, and each and every agent, consultant, attorney, auditor, or any party acting on behalf of the client/payer who will access or receive AdvancePCS' Confidential Information. No information disclosed shall be made available to any other party in the absence of a signed and executed confidentiality agreement between such party and AdvancePCS.

C. This Agreement is not intended to require AdvancePCS to breach the terms of any contract with a Client Plan, pharmaceutical manufacturer, retail pharmacy or other contractual party. If compliance by AdvancePCS with this Agreement would cause a breach of any such contract, AdvancePCS will use reasonable best efforts to obtain consent of the other contractual party to permit AdvancePCS to comply.

VI. INJUNCTION

A. AdvancePCS Disclosures

1. Relationships with Client Plans:

- (a) In any new contract with a Client Plan or in any amendment to an existing contract in which new terms and conditions (other than pricing terms and

renewal dates) are negotiated and documented, AdvancePCS will use reasonable best efforts to:

- (1) adequately and clearly describe the products and services that will be delivered or performed pursuant to the Client Plan contract;
- (2) clearly define the obligations of AdvancePCS and the Client Plan under the contract;
- (3) define in clear terms words or phrases that are used in the contract with Client Plans to describe price;
- (4) adequately and clearly describe the amounts to be paid by the Client Plan for products or services under the Client Plan contract;
- (5) disclose, where applicable, to Client Plans that Client Plans may pay more or less for brand and generic drugs at retail than AdvancePCS reimburses retail pharmacies for said drugs;
- (6) in any client contract that refers to MAC or uses MAC as a price marker, identify drugs comprising the MAC list applicable to the Client Plan at the time the contract is signed;
- (7) when using nationally recognized data sources and terms for Client Plan pricing, ensure that data sources and terms are defined in the contract with the Client Plan;
- (8) when using nationally recognized data sources and terms for Client Plan pricing, disclose to the Client Plan the circumstances under which AdvancePCS will utilize the data sources and terms.

- (b) Prices charged to Client Plans for Generic Drugs: AdvancePCS shall provide an updated MAC list applicable to the Client Plan as may be required by the client contract or otherwise reasonably requested by the Client Plan.
- (c) Nationally Recognized Data Sources and Pricing Terms: AdvancePCS will use nationally recognized data sources, such as First Data Bank and MediSpan, and terms for determining contracted pricing for drugs dispensed. When AdvancePCS uses these nationally recognized data sources and terms for Client Plan pricing, AdvancePCS shall:
 - (1) for any Client Plan, utilize the same data source for pricing to the Client Plan and for reimbursing the dispensing pharmacy for the same drug unless otherwise specified in the Client Plan contract; and
 - (2) if AdvancePCS makes a change in pricing for a drug to a Client Plan based on an update made by a nationally recognized drug source, AdvancePCS will make a simultaneous change to the reimbursement rate for the dispensing pharmacy for such drug to reflect such update.
- (d) **Client Plan Invoicing and Audits**
 - (1) Invoices sent to the Client Plan for retail and mail prescription claims shall clearly identify the price to be paid by the Client Plan.
 - (2) The Client Plan shall have access, upon request, to all information reasonably necessary to audit the price paid or confirm compliance

with the terms of the client contract as specified in the Client Plan contract.

(e) **Retail Pharmacy Contracting**

In any new contract with a retail pharmacy or in any amendment to an existing contract with a retail pharmacy in which new terms and conditions (other than pricing terms and renewal dates) are negotiated and documented:

- (1) AdvancePCS shall use its reasonable best efforts to include in its contract with retail pharmacies an express requirement that the retail pharmacy disclose to the Plan Participant if such pharmacy's U&C price for the particular drug dispensed is less than the applicable co-pay, unless the contract between AdvancePCS and the Client Plan provides otherwise.
- (2) AdvancePCS shall use its reasonable best efforts to include in the contract with the retail pharmacy an affirmative obligation requiring the retail pharmacy to allow the Plan Participant to pay either the co-pay or the U&C price, whichever is lower, if the Plan Participant's plan design so permits.

(f) **Manufacturer Payments**

- (1) AdvancePCS shall disclose to each Client Plan with an existing contract, and to each prospective Client Plan in advance of or upon entering into a contract with such Client Plan:
 - i. that AdvancePCS will solicit and receive Manufacturer Payments and that AdvancePCS may pass through those

payments to Client Plans or may retain those payments for itself, depending on the contract terms and whether the payments are attributable to the Client Plans; and

- ii. that AdvancePCS will report, quarterly and annually, on Manufacturer Payments, consistent with section (2) below.

- (2) Quarterly and Annual Disclosures: With respect to each Client Plan that has contracted to receive (directly or by credit) any Manufacturer Payments from AdvancePCS, for each AdvancePCS fiscal year during which the Client Plan receives any such Manufacturer Payments, AdvancePCS shall provide those Client Plans, for each AdvancePCS fiscal quarter and year, a Manufacturer Payments Report. AdvancePCS' Manufacturer Payment Reports shall identify, for the reported fiscal quarter or year (the "reporting period"), the information set forth below at (i) through (v). If the precise reported figure is not known by AdvancePCS at the time of its report, AdvancePCS shall provide its current best estimate of the reported information, provided that, with respect to each report, should the reported information subsequently need revision in accordance with generally accepted accounting principles, AdvancePCS will provide an update to the reported information to reflect that revision. Manufacturer Reports shall include:

- i. the dollar amount of AdvancePCS Total Product Revenue (as defined) for the reporting period;
 - ii. the dollar amount of total drug expenditures for the applicable Client Plan;
 - iii. all Manufacturer Payments earned by AdvancePCS for the reporting period expressed as a percentage range (within plus or minus three percent) of the AdvancePCS Total Product Revenue;
 - iv. the percentage of all Manufacturer Payments earned by AdvancePCS for the reporting period that were Manufacturer Formulary Payments; and
 - v. the percentage of all Manufacturer Payments received by AdvancePCS during the reporting period that were Manufacturer Additional Payments.
- (3) AdvancePCS' Manufacturer Payment Reports shall present the above information in a clear and conspicuous manner that serves to inform Client Plans of all Manufacturer Payments earned by AdvancePCS.

B. Payments to Clients

1. In any new Client Plan contract or in any amendment or renewal of an existing Client Plan contract, AdvancePCS shall not pay implementation or development fees and/or credits to a Client Plan unless such fees and/or credits to a Client Plan meet all of the following requirements:

- (a) Payments are for legitimate, necessary and commercially reasonable services related to the transition, administration or implementation of the client/payer contract, related to the purchase by the client/payer of clinical or other services offered by AdvancePCS or related to purchase discounts offered by AdvancePCS to the client/payer.
- (b) Services provided shall be clearly and adequately described and documented.
- (c) Payments paid for services provided shall be at fair market value.
- (d) AdvancePCS agrees to report to the United States Attorney for the Eastern District of Pennsylvania within a reasonable time any requirement by a client/payer, or their agent, broker, consultant, attorney, or other representative, to use any form of consideration that does not meet the criteria set forth in section (a) through (c) above as a condition to participation in the bidding process or as part of the consideration for the contract.
- (e) Nothing in this section shall otherwise prohibit AdvancePCS from selling or purchasing products or services to or from a client in the ordinary course of business.

C. Relationships with Pharmaceutical Manufacturers

1. With respect to any new contract with a pharmaceutical manufacturer or in any renewal where a new base contract is negotiated with a pharmaceutical manufacturer, AdvancePCS agrees that the terms of the contract shall clearly and accurately describe and differentiate, where applicable, the following payments:

- (a) Discounts;
- (b) Rebates;
- (c) Administrative fees paid by the manufacturer;
- (d) Fees for services provided by AdvancePCS to the manufacturer;
- (e) Fees received for the sale or provision of utilization data; and
- (f) Any other payments paid to or received by either party.

2. AdvancePCS agrees that rebates received from any manufacturer shall be supported by the submission of claim utilization data for each product for which a rebate is claimed so that the pharmaceutical manufacturer can determine the amount paid by product.

D. Relationships with Participants

With respect to AdvancePCS' pharmacies and its employed pharmacists, AdvancePCS agrees to the following:

1. Drug Interchanges

- (a) When a Plan Participant's Prescriber approves a Drug Interchange, AdvancePCS agrees to provide to the Plan Participant both a written communication that is included with the drug shipment and an electronic communication, as appropriate and when feasible. Both of these communications shall include the following:
 - (1) A disclosure that is separate from other prescription, health and safety information included with the drug shipment, that is in such size, color, contrast and location, that it is readily noticeable, readable and understandable and not obscured in any manner and in a location sufficient for a Plan Participant to read and

comprehend it. For purposes of this Consent Order, nothing in this section shall prevent AdvancePCS from disclosing prescription, health and safety information first;

- (2) A clear, conspicuous and understandable explanation that a Drug Interchange has been requested by AdvancePCS;
- (3) An explanation that following AdvancePCS' request, the Plan Participant's Prescriber approved and authorized the Drug Interchange;
- (4) A description of the circumstances under which the Originally Prescribed Drug will continue to be covered by the client/payer plan, if such is the case;
- (5) An identification of the drug that has been shipped and the drug for which the substitution was made;
- (6) Clear instructions on how to use the toll-free telephone number provided by AdvancePCS to call a pharmacist if the Plan Participant has any questions about the Drug Interchange. Upon request by the Prescriber, the same number will be provided to Prescribers for questions about a proposed Drug Interchange;
- (7) A clear explanation of the process the Plan Participant should follow to initiate a switchback, including the toll-free number that should be called to request a reversal of the Drug Interchange; and

- (8) A clear and conspicuous statement that the Plan Participant may decline the Drug Interchange in which case the Plan Participant will receive the Originally Prescribed Drug.
- (b) AdvancePCS agrees not to implement a Drug Interchange program if the cost to the Client Plan or Plan Participants is higher than the cost of the Originally Prescribed Drug, unless the Client Plan has agreed to such specific Drug Interchange.
- (c) AdvancePCS agrees not to initiate or propose a Drug Interchange if the Originally Prescribed Drug is identified as an NTI or NTR drug.
- (d) AdvancePCS agrees that it shall make no representation that the Plan Participant's Prescriber initiated the Drug Interchange.
- (e) AdvancePCS agrees that it shall not make or cause to be made any Drug Interchange solicitation to a Plan Participant who, within two years preceding the solicitation, and with respect to the same therapeutic class involved in the proposed Drug Interchange, has interchanged his or her drug following an AdvancePCS Drug Interchange solicitation but had the Interchange reversed, unless any of the proposed drugs in the current Drug Interchange solicitation were not among the proposed drugs in the prior Drug Interchange solicitation and were new drugs approved by the FDA after the Drug Interchange solicitation or were existing drugs approved for a new indication after the Drug Interchange solicitation, in which case AdvancePCS may make a Drug Interchange solicitation for the new proposed drug only.

2. Rejected Interchanges

- (a) AdvancePCS shall maintain a toll-free telephone number(s) Monday through Friday from the hours of 7:00 AM to 9:00 PM CT to field telephone calls from Plan Participants and Prescribers in response to AdvancePCS' interchange confirmations. AdvancePCS shall maintain an average response time of 60 seconds for such calls.
- (b) The Plan Participant or Prescriber shall have up to thirty (30) days following shipment of the interchanged drug to request a reversal to the Originally Prescribed Drug.
- (c) Upon reversal, AdvancePCS shall dispense the Originally Prescribed Drug.
- (d) AdvancePCS shall provide written confirmation to the physician that the approved interchange has been reversed and that the Originally Prescribed Drug has been dispensed.
- (e) AdvancePCS shall charge the Plan Participant only one co-pay, plus shipping and handling fees, if applicable, so that an approved, but reversed interchange will not increase Plan Participant costs beyond costs originally contemplated had AdvancePCS dispensed the Originally Prescribed Drug.
- (f) Unless otherwise agreed in the contract, in the event of a reversed interchange, AdvancePCS will also credit the client for the proposed drug and shall charge the client only for the cost of the prescribed drug that is ultimately dispensed.

- (g) Unless otherwise provided by contract with a client/payer, AdvancePCS shall also bear the expense of shipping the proposed drug back, if applicable, to AdvancePCS (either by offset or by reversing and crediting the initial co-pay).
- (h) AdvancePCS agrees to document and retain for a period of at least two years any information related to the reversal of a proposed Drug Interchange.
- (i) AdvancePCS agrees that it will monitor requests to reverse an approved Drug Interchange and, if the reversal rate exceeds 10% on an aggregate basis for all Plan Participants for any calendar quarter related to Drug Interchanges performed in that calendar quarter, AdvancePCS will discontinue such interchange.
- (j) Whenever a Drug Interchange is considered for a Generic Equivalent, AdvancePCS agrees to request that a generic drug be prescribed, if one exists, before requesting that another brand drug be substituted.
- (k) On an annual basis, AdvancePCS agrees that it will report to the AdvancePCS P&T Committee, as appropriate, an aggregate summary of all participant-reported adverse medication events and reversal rates associated with a Drug Interchange.

3. Retail Pharmacies

Client Plans may participate in AdvancePCS' Performance Rx Drug Program, a program administered by retail pharmacies which is designed to inform the Plan Participant about alternative products that are therapeutically equivalent to the prescribed drug, preferred on

AdvancePCS' formulary and less expensive for the Client Plan. AdvancePCS agrees to use reasonable best efforts to include in its contract with retail pharmacies administering the program a requirement that the retail pharmacy:

- (a) Disclose to the Plan Participant:
 - (1) a description of the program;
 - (2) that participation in the program is voluntary and that the Plan Participant may choose whether or not to participate; and
 - (3) that the retail pharmacy will be compensated for the time and effort spent discussing the program with the Plan Participant and the Plan Participant's Prescriber.
- (b) Disclose to the Prescriber:
 - (1) that AdvancePCS administers the Plan Participant's pharmacy benefit plan;
 - (2) that the retail pharmacy will be compensated for the time and effort spent discussing the program with the Plan Participant and the Plan Participant's Prescriber;
 - (3) the name and manufacturer of the Originally Prescribed Drug and the suggested alternative drug; and,
 - (4) the name of the pharmacist.
- (c) Document the program services that were performed, the date the services were performed and the name of the pharmacist performing the services.

- (d) Will be subject to monitoring by AdvancePCS for compliance with the program and that the pharmacy may be removed from the program for any acts of misconduct.

4. AdvancePCS' Payment of Drug Interchange-Related Health Care Costs

- (a) Within thirty days of receipt of an appropriate claims form for such costs, AdvancePCS shall pay all requested Drug Interchange-Related Health Care Costs incurred by a Plan Participant by reimbursing the Plan Participant for such costs not exceeding \$200.00. For any amount exceeding \$200.00 requested for such costs, AdvancePCS may, in its sole discretion, choose to have an independent third party selected by AdvancePCS review the Drug Interchange-Related Health Care Costs requested by a Plan Participant with respect to any particular Drug Interchange. If a determination is made that the costs requested qualify as Drug Interchange-Related Health Care Costs, then AdvancePCS shall pay all remaining Drug Interchange-Related Health Care Costs within sixty days of original receipt of the claim form for such costs.
- (b) AdvancePCS shall enact and follow a procedure for reimbursing Plan Participants such costs, by which AdvancePCS shall, without limitation,
 - (1) permit Plan Participants, Prescribers or treating physicians to request such reimbursement, by phone or in writing, and (2) upon such request, provide a single-page claim form to Plan Participants (with instructions) to request reimbursement. For reimbursement requests, AdvancePCS may (but need not) require that the Plan Participant's reimbursement claim provide information showing that Drug Interchange-Related Health Care

Costs were incurred. This requirement must be satisfied by a physician or Prescriber notation at a designated place on the claim form which clearly states that the cost was directly due to the Drug Interchange. AdvancePCS shall not prevent or discourage Plan Participants or physicians from requesting or receiving reimbursement for Drug Interchange-Related Health Care Costs in accordance with this provision.

- (c) AdvancePCS' written communications to both Prescribers and Plan Participants concerning Drug Interchanges, as set forth below, shall clearly and conspicuously disclose AdvancePCS policy, consistent with this Section, with respect to Drug Interchange-Related Health Care Costs. AdvancePCS telephone communications with Prescribers and Plan Participants concerning Drug Interchanges, as set forth below, shall communicate the existence of AdvancePCS' policy with respect to Drug Interchange-Related Health Care Costs. In its communications with Prescribers, Plan Participants and Client Plans, AdvancePCS shall not misrepresent its policy with respect to Drug Interchange-Related Health Care Costs.
- (d) AdvancePCS, while complying with the timely reimbursement requirement set forth in (a) above, may, in its sole discretion, choose to have an independent third party chosen by AdvancePCS to review the Drug Interchange-Related Health Care Costs requested by a Plan Participant with respect to any particular Drug Interchange. If a determination is made that the costs were not Drug Interchange-Related Health Care Costs, nothing herein

shall prevent AdvancePCS from pursuing any legal remedies AdvancePCS may have against the Plan Participant and any other party involved.

E. Relationships with Brokers and TPAs

With respect to these relationships, AdvancePCS agrees that any new contract with a broker or TPA or any renewal where a new base contract is negotiated, the contract with the broker or TPA shall:

1. clearly set forth and specifically describe the services that the party will perform for AdvancePCS;
2. describe the payment terms to which the party is entitled under the agreement;
3. require the party to certify to AdvancePCS that it has disclosed to client/payer that it has a relationship with AdvancePCS and the terms of payment that it has negotiated with AdvancePCS; and
4. disclose to client/payer the fact that a relationship with a broker or TPA exists.

F. Relationships with P&T Committee

1. An independent P&T Committee shall be maintained that is governed by the P&T Committee Charter.
2. The P&T Committee shall be comprised of no fewer than 10 members, all of whom shall be physicians, pharmacists, or other health care professionals, and a majority of whom are actively practicing.
3. AdvancePCS agrees that no voting member of the P&T Committee shall be an employee of AdvancePCS or a related corporate entity.
4. No Drug Interchange Program shall be implemented unless the P&T Committee has approved such interchange.

5. The P&T Committee shall review and approve of all Drug Lists developed by AdvancePCS for adoption by client/payers.

6. In the event the P&T Committee approves a Drug Interchange Program with conditions, AdvancePCS shall provide a complete description of such conditions to the Prescriber at the time of the request for an interchange.

7. AdvancePCS agrees that all P&T Committee members shall be required to disclose annually in writing whether any financial relationship exists with a pharmaceutical manufacturer.

8. Committee members shall be required to provide notice of any changes to the annual written disclosure prior to a formal or ad hoc meeting.

9. Members shall not be entitled to vote on any matter before the Committee where the member has a financial relationship with a pharmaceutical manufacturer whose product is under consideration for any action to be taken by the Committee.

10. All voting members of the P&T Committee shall be independent contractors who have executed a written agreement that describes the role and responsibility of P&T Committee members.

G. Relationships with Pharmacists and Physicians

With respect to AdvancePCS' pharmacies and its employed pharmacists, AdvancePCS agrees to the following:

1. AdvancePCS agrees to adopt the Code of Ethics of the American Pharmacists Association that is in effect on the date of this agreement for its employed pharmacists ("APhA Code of Ethics") and agrees to adopt the American Pharmacists Association Principles in effect on the date of this agreement ("APhA Principles").

2. No AdvancePCS employee supervisor or manager shall instruct any employee to engage in conduct which is inconsistent with the APhA Code of Ethics, referenced above, or state pharmacy law and regulations.

3. AdvancePCS shall make available to its mail order pharmacy employees, clients/payers and Plan Participants' copies (which may be in electronic form or available on a web site) of the APhA Code of Ethics and APhA Principles, both referenced above in Section 1.

4. AdvancePCS shall require its pharmacies, pharmacists, pharmacy technicians, and other employees to comply with all state law requirements governing their professional practice.

5. AdvancePCS will support the right of all its pharmacists to form an independent professional judgment to determine whether a Drug Interchange is clinically inappropriate for the Plan Participant.

6. AdvancePCS shall not interchange a Plan Participant's drug absent express verifiable authorization from the Prescriber, as communicated (a) directly by the Prescriber (in writing or verbally) or (b) by a person who affirms (in writing or verbally) that the interchange has been authorized by the Prescriber. If such authorization is by a person other than the Prescriber and is verbal, AdvancePCS shall document that person's first and last name, title or position, and date and time.

7. AdvancePCS agrees to record, where permitted by law, all conversations with the doctor's office where an interchange is solicited. Such recordings shall be maintained and stored for at least two years.

8. If as a result of the interchange solicitation the Prescriber calls AdvancePCS to request additional information regarding the clinical appropriateness of such proposed interchange, a pharmacist shall respond to the prescribing physician's call.

9. AdvancePCS shall maintain records memorializing, with respect to each interchange, how express verifiable authorization was obtained, including the name of the person providing the express verifiable authorization of the interchange (to the extent that the last name is provided, it will be included); whether the authorization was written or verbal and, if verbal and by a person other than the Prescriber, that person's title or position, if provided and the date and time.

10. AdvancePCS agrees not to request an interchange for any drug identified as an NTI or NTR drug.

11. AdvancePCS shall not make any savings claim for a Drug Interchange unless such savings claims are substantiated. Such savings claims shall be substantiated by either the minimum or actual cost savings. If a savings claim is made, the minimum or actual savings must be disclosed. When making these disclosures, AdvancePCS may reasonably rely on information provided by the Client Plan with respect to eligibility and Co-payments, irrespective of deductibles and caps.

12. In the event that the Prescriber or his representative or the Plan Participant declines a participant-specific interchange request, AdvancePCS agrees that for a period of two years the identical interchange solicitation will not be solicited or made.

13. All materials funded by pharmaceutical manufacturers shall clearly disclose the source of such funding.

14. AdvancePCS shall, on an annual basis, communicate to those physicians visited by Clinical Consultants in writing, by mail and by hand delivery of the same letter on the first office visit to the physician, that part of the Consultants' office visits are funded by pharmaceutical manufacturers. These written communications with the physicians shall:

- (a) include a personalized address to the physician;
- (b) identify the Clinical Consultant who will be visiting the physician;
- (c) clearly outline the purpose of the Clinical Consultant's office visit; and
- (d) clearly identify that part of the Clinical Consultant's messaging and activities during the office visits are funded by pharmaceutical manufacturers.

VII. GENERAL PROVISIONS

A. Scope of Consent Order

The injunctive provisions of this Consent Order are entered into pursuant to the Federal Injunctive Statute, 18 U.S.C. § 1345, and are applicable to AdvancePCS, its officers and employees, and all those acting under the direction and on behalf of AdvancePCS who receive actual notice of this Order by personal service or otherwise, whether acting directly or through any entity, corporation, subsidiary, division, or other device.

B. Release of Claims

1. By its execution to the Consent to Entry of Order attached hereto, and in consideration of and in accordance with AdvancePCS' agreement to be legally bound by the injunctive provisions contained in the instant Consent Order, the United States, upon the Effective Date (as defined in Section VII.I. below), releases and forever discharges AdvancePCS, its past and present subsidiaries, affiliates, predecessors and successors and each of the past and present officers, directors, attorneys, insurers, and assigns of any of the foregoing (collectively, the "Released Parties") from all manner of claims for injunctive relief under 18 U.S.C. § 1345, or any other potential theory for injunctive relief, related to the "Covered Conduct" set forth in paragraph VII.C., below, in law or equity, that the United States ever had,

now has or hereafter can, shall or may have, whether known or unknown, suspected or unsuspected, and/or contingent or non-contingent, against any Released Party (the “Released Claims”).

2. This Consent Order may be pleaded as a full and complete defense to any claim released hereunder that may be instituted, prosecuted, or attempted with respect to any of the Released Claims.

C. Covered Conduct

The specific conduct covered by this Consent Order is for the period January 1, 1996 through the Effective Date of this Consent Order and is:

1. all pharmacy and operational practices and procedures at AdvancePCS’ mail order pharmacies, retail pharmacies, customer care call centers, corporate offices, and clinical intervention centers, including but not limited to, Drug Interchanges, the type and amount of contact between such AdvancePCS facilities and personnel (including without limitation Clinical Consultants) and physicians, patients, and Plan Participants, and personnel practices and activities related to productivity requirements and quotas;
2. rebates and other payments solicited and/or received by AdvancePCS from pharmaceutical manufacturers;
3. performance and operation of the AdvancePCS Pharmacy and Therapeutics Committee;
4. payments to brokers and consultants who perform services for AdvancePCS customers or potential customers;
5. AdvancePCS customer contract performance guarantees, incentives and penalties;

6. AdvancePCS customer contract pricing provisions for retail pharmacy prescription claims;

7. AdvancePCS contract reimbursement rate pricing provisions with retail pharmacies;

8. payments by AdvancePCS to customers and potential customers in the form of implementation fees or credits, stock warrants, stock equity, and cash in connection with entry of a contract or renewal of a contract; and

9. to the extent not otherwise specified, the Covered Conduct identified in Paragraph R of the Settlement Agreement between AdvancePCS and the United States in United States ex rel. Mary Jean Brown and Kevin Waite, et al. v. AdvancePCS, Civil Action No. 02-9236 (E.D. Pa.); United States ex rel. Karl S. Schumann v. AdvancePCS, et al., Civil Action No. 03-5425 (E.D. Pa.) (“Settlement Agreement”).

D. Specifically Excluded Conduct

The United States specifically acknowledges that the Consent Order does not encompass a settlement or release of any claim, right, or cause of action for monetary damages, restitution, or penalties under the False Claims Act, 31 U.S.C. § 3729-3733; the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a; Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-3812; the Public Contract Anti-Kickback Act, 41 U.S.C. § 55(a)(1)(B), and common law causes of action for fraud, unjust enrichment, payment by mistake, or breach of contract, for the Covered Conduct described above except to the extent such conduct was identified in Paragraph R of the Settlement Agreement.

In addition, except as provided in this Consent Order or in the Settlement Agreement, the United States specifically does not release AdvancePCS and all of its

subsidiaries, affiliates, assigns, corporate predecessors and successors from any and all of the following:

1. any criminal, civil, or administrative claims arising under Title 26, U.S. Code (Internal Revenue Code);
2. any liability to the United States (or agencies thereof) for any conduct other than the Covered Conduct in this Consent Order and the Settlement Agreement;
3. any claims based upon obligations created by this Consent Order;
4. any administrative liability, including exclusion from federal health care programs, except as provided in the Settlement Agreement;
5. any express or implied warranty claims or other claims for defective or deficient products and services provided by AdvancePCS;
6. any claims for personal injury or property damage or for other consequential damages arising from the Covered Conduct;
7. any claims based on a failure to deliver items or services due on a timely basis;
8. any civil claims against individuals except as provided in the Settlement Agreement;
9. any administrative claims against individuals, including current and former directors, officers, and employees of AdvancePCS, its subsidiaries, affiliates, assigns, corporate predecessors and successors; and
10. any criminal claims against AdvancePCS, its subsidiaries, affiliates, assigns, corporate predecessors and successors, individuals, including current and former directors, officers, and employees of AdvancePCS, its subsidiaries, affiliates, assigns, corporate predecessors and successors.

E. Resolution of Injunctive Claims

The United States agrees that it shall not proceed with or institute any civil action or proceeding based upon 18 U.S.C. § 1345 or any other theory of injunctive relief, against AdvancePCS, or seek injunctive relief for any conduct undertaken or omissions prior to the Effective Date which relates to the Covered Conduct. AdvancePCS may plead this Order as a full and complete defense to any claim, whether class, individual, or otherwise in nature, released hereunder that may be instituted, prosecuted, or attempted by the United States with respect to the Covered Conduct.

Moreover, the United States does not release any claim arising under statutes, laws, or regulations other than those identified in Section VII.B. herein, and arising out of the Covered Conduct which is the subject matter of this Consent Order. In addition, the United States does not release any claim, right or cause of action that could be brought by any person or entity other than the United States. The United States may institute an action or proceeding to enforce the terms and provisions of this Consent Order or take action based on future conduct by AdvancePCS and its subsidiaries, affiliates, assigns, corporate predecessors and successors.

F. Preservation of Law Enforcement Action

Nothing herein precludes the United States from enforcing the provisions of this Consent Order, or from pursuing its claims with respect to the acts or practices of AdvancePCS not covered by this Consent Order or any acts or practices of AdvancePCS conducted after the Effective Date of this Consent Order.

G. Compliance with and Application of Federal Law

Nothing in this Agreement shall relieve AdvancePCS of its obligation to comply with applicable laws of the United States nor constitutes authorization by the United States for AdvancePCS to engage in acts and practices prohibited by such laws.

H. Non-Approval of Conduct

Nothing herein constitutes approval by the United States of AdvancePCS' therapeutic interchange program or other business practices. AdvancePCS shall not make any representation contrary to this paragraph.

I. Effective Date

The "Effective Date" of the Consent Order shall be the latest of the following dates: the date that the last signatory to the Settlement Agreement has executed the Settlement Agreement; the date that the Court enters the Consent Order; and the date that the Court enters the Stipulations of Dismissal. In the event that the Consent Order and the Settlement Agreement do not become effective, this Consent Order and the Settlement Agreement shall be treated as materials received pursuant to Fed. R. Evid. 408.

J. Effective Date of Section VI.

Notwithstanding that AdvancePCS shall endeavor to comply with all injunctive terms in Section VI as promptly as practicable, the terms of Section VI shall be implemented on or before 120 days after the Effective Date.

VIII. COMPLIANCE PROVISIONS

A. Within 60 days after the Effective Date of the Order, AdvancePCS must provide a copy of this Order and obtain a signed and dated acknowledgement of receipt from:

1. AdvancePCS officers and directors;

2. AdvancePCS senior management;
3. all managers within each of AdvancePCS' mail order pharmacies and clinical intervention centers and pharmacists involved in Drug Interchange communications with Plan Participants or Prescribers; and
4. each customer service representative to whom a telephone call concerning Drug Interchanges may be directed in the routine routing of calls, if applicable.

B. For five years from the Effective Date, AdvancePCS shall provide a copy of this Order and obtain a signed and dated acknowledgement of receipt from future personnel described in A.1 through A.4 of this section VIII within 30 days after the person assumes such position or responsibility.

C. AdvancePCS shall make this Order accessible to Client Plans and Plan Participants through its website.

D. The compliance committee of AdvancePCS shall assess, on a quarterly basis, AdvancePCS' compliance with this Order. The compliance committee, or its delegate, shall develop, maintain and distribute methods and procedures ("M&Ps") establishing a code of conduct consistent with APhA Code of Ethics and state pharmacy law and regulations for all AdvancePCS employees engaged in Drug Interchange programs. The M&Ps must be designed to establish quality standards for the manner in which information is disseminated to Prescribers and Plan Participants by AdvancePCS employees regarding Drug Interchanges.

E. AdvancePCS will review the M&Ps annually with their pharmacists and all other personnel involved with the Drug Interchange program. As warranted, the compliance committee will review and/or recommend initiatives to ensure that AdvancePCS' Drug

Interchange practices and disclosures to Prescribers, Plan Participants and Client Plans comply with this Order.

F. AdvancePCS shall create and retain for a period of five (5) years following the date of creation, books and records that in reasonable detail accurately reflect AdvancePCS' compliance with this Order. These records must include, but are not limited to, the following:

1. documents reflecting the current addresses, telephone numbers, fax numbers and email addresses for AdvancePCS and its subsidiaries, including all covered mail order pharmacies and clinical intervention centers;
2. the original, signed and dated acknowledgments of the receipt of the Order described in section VIII.A.1.;
3. documents provided to or received from Client Plans concerning all Client Plan instructions, if any, concerning opting out of any provisions of this Order;
4. an exemplar of each written notice sent to Prescribers regarding Drug Interchanges;
5. an exemplar of each written notice sent to Plan Participants regarding Drug Interchanges;
6. a copy of each script used in telephonic communications with Prescribers and Plan Participants relating to Drug Interchanges;
7. a copy of all training materials used to inform employees of the requirements of this Order;
8. a copy of all M&Ps developed by the compliance committee or its delegate;
9. documents concerning the drugs subject to Drug Interchanges;
10. documents reflecting Plan Participant rejections of Drug Interchanges; and

11. exemplars of AdvancePCS' quarterly and annual disclosures to Client Plans required by section VI.A.1.(f) of this Order.

G. For a period of five years beginning on the Effective Date of this Order, and within thirty (30) days of a written request by the United States, AdvancePCS shall provide to the United States:

1. copies of the documents described in the preceding paragraphs; and
2. such other records and documents as the United States determines reasonably bear on compliance with the Order.

H. Nothing in this Order limits the United States' lawful use of compulsory process to investigate whether AdvancePCS has violated any provision of law enforced by the United States.

IX. ADMINISTRATIVE PROVISIONS

A. Jurisdiction of this matter is retained for all purposes, including but not limited to, the purpose of enabling any of the parties to this Order to apply to the Court at any time for such further orders or directives as may be necessary or appropriate for the interpretation or modification of this Order, for the enforcement of compliance therewith, or for the punishment of violations thereof.

B. Any party to this Consent Order may petition the Court for interpretation, modification, or enforcement of this Consent Order on thirty (30) days' notice to all other parties to this Consent Order. Modification may be appropriate if the underlying facts and circumstances have changed in any material respect. In addition, the parties by stipulation may agree to a modification of this Consent Order, which agreement shall be presented to this Court for consideration; provided that the parties may jointly agree to a modification only by a written

instrument signed by or on behalf of both AdvancePCS and the United States. Any party seeking a stipulation for a modification of this Consent Order, shall send a written request for agreement to the other party at least 30 days prior to filing a motion with the Court for such modification. Within 30 days of receipt of a written request for agreement to modify, the receiving party shall notify the requesting party in writing if the receiving party agrees to the requested modification.

C. If, after the date of entry of this Consent Order, the United States, its Attorney General, or any agency of the United States enacts or promulgates legislation, rules or regulations with respect to matters governed by this Consent Order that conflict with any provision of this Consent Order, or if the applicable law of the United States shall otherwise change so as to conflict with any provision of this Consent Order, the United States shall not unreasonably withhold its consent to the modification of such provision to the extent necessary to eliminate such conflict. Laws, rules, or regulations, or other change in Federal law, with respect to the matters governed by this Consent Order, will be considered to conflict with a provision of this Consent Order if AdvancePCS cannot reasonably comply with both such law, rule, or regulation and an applicable provision of this Consent Order, or if such law, rule or regulation authorizes conduct otherwise prohibited by this Consent Order.

D. AdvancePCS, on behalf of its subsidiaries, affiliates, assigns, predecessors and successors fully and finally releases, waives, and discharges the United States, its agencies, employees, servants, and agents from claims (including attorneys' fees, costs, and expenses of every kind and however denominated) which AdvancePCS has asserted, could have asserted, or may assert in the future against the United States, its agencies, employees, servants and agents,

relating to or arising from the United States' investigation and prosecution of the Covered Conduct identified in the Consent Order.

E. By entering this Consent Order, AdvancePCS does not admit the allegations made in United States ex rel. Mary Jean Brown and Kevin Waite, et al. v. AdvancePCS, Civil Action No. 02-9236 (E.D. Pa.); United States ex rel. Karl S. Schumann v. AdvancePCS, et al., Civil Action No. 03-5425 (E.D. Pa.), and does not admit fault or liability for claims asserted in these actions or for any other claims.

F. AdvancePCS agrees to the following:

1. Each party to this Consent Order shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance pursuant to the terms of this Order.

2. Each of the United States and AdvancePCS represent that it has given its consent to this Order freely and voluntarily without any degree of duress or compulsion whatsoever.

3. This Consent Order is governed by the laws of the United States, including without limitation any statutes of limitation. AdvancePCS and the United States agree that the exclusive jurisdiction and venue for any dispute arising between and among the Parties under this Consent Order shall be the United States District Court for the Eastern District of Pennsylvania.

4. Facsimiles of signatures shall constitute acceptable binding signatures for purposes of the Consent Order.

5. This Consent Order shall be binding on all successors, transferees, heirs and assigns of the United States and AdvancePCS.


X. TERMINATION

The provisions of this Order will terminate five years from the Effective Date.

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DATED:

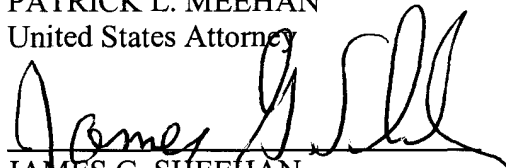
BY:



PATRICK L. MEEHAN
United States Attorney

DATED:

BY:



JAMES G. SHEEHAN
Associate United States Attorney

DATED:

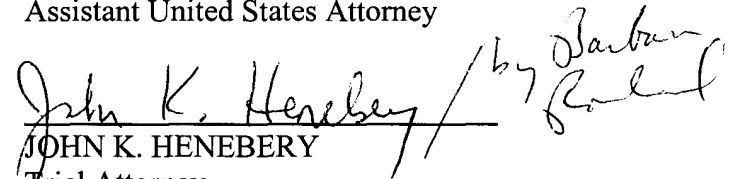
BY:



BARBARA ROWLAND
Assistant United States Attorney

DATED:

BY:



JOHN K. HENEBERY
Trial Attorney
United States Department of Justice – Civil
Division, Commercial Litigation, Fraud
Section

AdvancePCS

DATED:

BY:

EXECUTIVE SIGNATORY
AdvancePCS

Approved and so ordered.

Dated: _____

By the Court:

NORMA L. SHAPIRO
Judge, United States District Court

DATED:

BY:

PATRICK L. MEEHAN
United States Attorney

DATED:

BY:

JAMES G. SHEEHAN
Associate United States Attorney

DATED:

BY:

BARBARA ROWLAND
Assistant United States Attorney

DATED:

BY:

JOHN K. HENEBERY
Trial Attorney
United States Department of Justice – Civil
Division, Commercial Litigation, Fraud
Section

AdvancePCS

DATED:

BY:


EXECUTIVE SIGNATORY
AdvancePCS

Approved and so ordered.

Dated: _____

By the Court:

NORMA L. SHAPIRO
Judge, United States District Court

CONSENT TO ENTRY OF ORDER

AdvancePCS, through the undersigned officer duly authorized by AdvancePCS, and the United States of America (the “United States”), through the undersigned individuals duly authorized by the United States, hereby:

1) admit to the jurisdiction of the Court over the persons and subject matter of this action,

2) consent to the entry of an Order for Injunction, including the release contained therein, regarding the claims at issue between the United States and AdvancePCS, in the attached form hereto,

3) certify, respectively, that its duly authorized representative has personally read and understands the Consent Order of Court for Injunction and Settlement (the “Consent Order”) to which this Consent of Entry of Order is attached and has consulted with counsel, and knowingly and voluntarily enters into this consent judgment,

4) state that no promise of any kind of nature whatsoever (other than the written terms of the Consent Order) was made to it to induce it to enter into this Consent to Entry of Order, that it has entered into this Consent to Entry of Order voluntarily, and that this Consent to Entry of Order, together with the Consent Order, constitutes the entire agreement between AdvancePCS and the United States, and

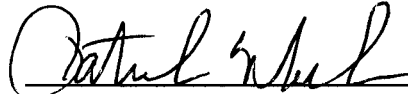
5) agree that this Consent to Entry of Order may be executed in any number of counterparts, including by facsimile, and by the different parties hereto on the same or separate

counterparts, each of which shall be deemed to be an original but all of which counterparts shall together constitute but one and the same instrument.

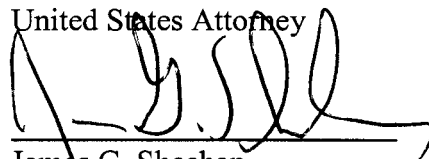
BY:

AdvancePCS
Executive Signatory

BY:



PATRICK L. MEEHAN
United States Attorney



James G. Sheehan
Associate United States Attorney



Barbara Rowland
Assistant United States Attorney
615 Chestnut St., Ste. 1250
Philadelphia, PA 19106
(215) 861-8311 Telephone
(215) 861-8439 Facsimile

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BY:



AdvancePCS
Executive Signatory

BY:

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